

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

BRUCE N. SAFFRAN, Ph.D., M.D.,  
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION.  
Defendant.

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CIVIL ACTION NO. 2-05-CV-547 (TJW)

**ORDER**

Before the court is Plaintiff's Motion to Strike Defendant's Amended Invalidity Contentions Allegedly Served Pursuant to Patent Rule 3-6(a)(2)(B) and Corresponding Portions of the Expert Report of Harold B. Hopfenberg (#89)(the "Motion to Strike") and the defendant's Motion for Leave to Amend (#107)("Motion for Leave").<sup>1</sup> For the following reasons, the Motion to Strike is GRANTED, and the Motion for Leave is DENIED.

**I. BACKGROUND**

Bruce N. Saffran, Ph.D., M.D., ("Saffran") filed this suit on December 16, 2005. Pursuant to the Local Rules, the defendant, Boston Scientific Corporation ("BSC") filed its Invalidity Contentions on December 4, 2006. The parties exchanged their claim construction positions on March 28, 2007 and submitted their joint claim construction and pre-hearing statement to the court on June 15, 2007. The court conducted a claim construction hearing on July 26, 2007. The court issued its claim construction order on September 28, 2007. Pursuant to the docket control order, opening expert witness reports were due on October 23, 2007, technical expert rebuttal reports were due on November 6, 2007, expert deposition discovery closed on December 20, 2007, and the

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<sup>1</sup>BSC drafted the Motion for Leave in the body of its opposition to the Motion to Strike.

deadline for identifying trial witnesses was November 20, 2007.<sup>2</sup> On November 16, 2007, approximately six weeks before the original date of jury selection, BSC served amended Invalidity Contentions. The new contentions form the basis for the Motion to Strike.

In its November 16, 2007 amendment, BSC modified its Invalidity Contentions in part as follows:<sup>3</sup>

1. BSC added the Lambert PCT Application.<sup>4</sup>
2. BSC added the 1994 Lambert Abstract.
3. BSC added the Ding Patent.
4. BSC added the “prior work” of Dr. Thomas L. Lambert and Dr. Vishva Dev.
5. BSC added the Dev abstract.
6. BSC added the Dev article.
7. BSC added the Lambert ‘246 Patent.
8. BSC added the theory that the ‘760 patent does not enable a combination to make a layer of flexible material that is minimally porous to macromolecules or a specific material to be used as the treating material.

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<sup>2</sup>The court notes that the parties jointly asked for—and received—extensions for these specific dates.

<sup>3</sup>The court created this list using the summary of changes “made in BSC’s Amended Invalidity Contentions” provided by BSC to Saffran and attached as Exhibit 8 to the Motion to Strike (the “Chart”). The court’s summary is not exhaustive.

<sup>4</sup>For brevity, the court uses the abbreviations for prior art references that BSC used in its Amended Invalidity Contentions.

9. BSC added the theory that the '760 patent does not enable "us[ing] a hydrophobic drug and hydrophobic polymer to perform the function of 'releasing a treating material toward the damaged tissue' in a damaged blood vessel" or "a specific combination of a specific hydrophobic drug and a specific hydrophobic polymer."

10. BSC added the theory that the '760 does not enable attaching a therapeutically effective amount of a treating material to a layer of material that is minimally porous to macromolecules.

11. BSC added the contention that Aebischer '486, Schwartz, Scott and the 1989 Aebischer article anticipate claim 9.

12. BSC added the contention that the asserted claims are indefinite if "chemical bonds and linkages" encompasses more than "chemical bonds."

13. BSC added the contention the '760 patent is indefinite as it relates to the presence or absence of a "sheet," "stents with large, uncovered gaps between the stent struts through which cells and macromolecules may pass," and "a layer of flexible material that is minimally porous to macromolecules" or "evenly dispersed within a 'layer of flexible material that is minimally porous to macromolecules.'"

BSC offered an explanation(s) for each amendment in the Chart. BSC seeks to justify its amendments by pointing to: (1) the court's construction for the claim term "material release means;"

(2) its assertion that the additional prior art references provide only “additional information about a construction previously disclosed;” (3) the court’s construction for the claim term “small molecules;” (4) the court’s construction for the term “flexible fixation device;” (5) the court’s construction for the claim term “device;” and (6) the court’s construction for the claim term “minimally porous to macromolecules.”<sup>5</sup>

## II. MOTION TO STRIKE

Saffran asks the court to strike BSC’s Amended Invalidity Contentions as well as the corresponding portions of Dr. Hopfenberg’s expert report. BSC argues that its amendments to the Invalidity Contentions were *necessitated* by the court’s *unexpected* claim constructions and that much of the information disclosed in the new prior art references is disclosed in the original Invalidity Contentions. BSC further argues that Saffran’s expert reports necessitated BSC’s amendments to its original Invalidity Contentions. These arguments are without merit and could be classified as frivolous. The amendments to the Invalidity Contentions are untimely, and the court strikes them as well as the corresponding portions of BSC’s expert report(s).

### A. Unexpected Claim Constructions

First, the court addresses BSC’s argument that the court’s claim constructions were unexpected to such a degree that they forced BSC to amend its Invalidity Contentions. Local Patent Rule 3-6(a)(2)(B) permits a party to amend its invalidity contentions without leave of court within 50 days of the court’s claim construction order when the party believes in good faith that the court’s

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<sup>5</sup>The parties submitted an agreed construction for the claim term “small molecules.” The court declined to construe the terms “flexible fixation device,” “device,” and minimally porous to macromolecules.”

claim construction so requires. The court emphasizes that the amending party must believe *in good faith* that the court's claim construction requires the amendment. BSC has not shown that it acted in good faith.

The purpose of requiring preliminary contentions is to “require the parties to crystallize their theories of the case early in litigation.” *Nike, Inc. v. Adidas America, Inc.*, 479 F.Supp.2d 664, 667 (E.D. Tex. 2007)(citing *02 Micro International Ltd. v. Monolithic Power Systems*, 476 F.3d 1355, 1364 (Fed. Cir. 2006). A party is permitted to amend its contentions in response to an *unexpected* claim construction, not simply a construction with which the party disagrees. *See Nike, Inc.*, 479 F.Supp. 2d at 667-668 (emphasis added).

In the present case, the court issued its claim construction order on September 28, 2007. The court adopted the parties' agreed constructions for 4 terms, construed 4 terms,<sup>6</sup> and held that the remaining disputed terms did not need construction. However, out of all of the claim term constructions BSC alleges necessitated the amendments, the only term construed by the court independent of the parties' agreement was “material release means.” BSC alleges that the court's construction of “small molecules” necessitated a belated amendment, but the court simply adopted the parties' *agreed* construction for that claim term. Finally, BSC maintains that the court's decision that the jury could ascertain the plain meaning of “flexible fixation device,” “device,” and “minimally porous to macromolecules”<sup>7</sup> was so unexpected that BSC had to amend its invalidity contentions. These arguments are rejected and could be described as specious.

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<sup>6</sup>The court found “directional” and “unidirectional” to be synonymous as used in claims 1, 8, and 15.

<sup>7</sup>The court construed the term “macromolecules.”

Here, the court's claim construction was foreseeable by BSC. BSC has known of Saffran's proposed claim construction for "material release means" since March 28, 2007, but it did not, however, seek to amend when it learned of that position. As noted in BSC's opposition brief, the court "essentially adopted Saffran's proposed structure for the material release means elements" and concluded that the identified structure was "chemical bonds and linkages." Opp. Brf. at 2. BSC cannot argue in good faith that the court's construction of "material release means" was unexpected in these circumstances. Even worse, BSC suggest that it was "surprised" by the court's adoption of the parties' agreed construction of "small molecules." BSC could hardly be caught off-guard by a construction it advocated. Finally, BSC has not explained, how, if at all, the court's decision not to construe the other claim terms justifies amending BSC's invalidity contentions.

BSC argues that Saffran cannot claim prejudice because it fully briefed the relevant motion(s) for summary judgment for invalidity, which include theories advanced by BSC in its Amended Invalidity Contentions. This argument asks the court to create an incentive for parties who improperly amend their contentions to file corresponding motions for summary judgment and to effectively punish parties for responding to motions for summary judgment. The court declines to facilitate improper conduct and rejects BSC's argument.

#### **B. Saffran's Infringement Contentions**

In addition, BSC argues that Saffran effectively amended its Infringement Contentions via its expert reports, particularly Dr. Freeman's expert report. BSC alleges that Dr. Freeman expanded the scope of the Infringement Contentions and that this justifies the amendments to the Invalidity Contentions.

The passage in particular to which BSC objects is:

Chemical bonds and linkages between paclitaxel and SIBS polymer (e.g., hydrophobic bonds, hydrogen bonds, and Pi-Pi bonds) serve to restrain paclitaxel in the SIBS layer until the layer is placed adjacent to damaged vascular tissue. . . The environment of the damaged tissue is more favorable to paclitaxel and therefore the chemical bonds and linkages between paclitaxel and SIBS are broken and paclitaxel is released toward the damaged tissue.

Freemen Report at 5/25.

The court rejects BSC's arguments. A cursory inspection of Saffran's Infringement Contentions shows that, while the expert report is more detailed, Saffran's Infringement Contentions encompass the passages objected to by BSC.

For instance, Saffran's Infringement Contentions state:

The Taxus product couples a hydrophobic polymer and a hydrophobic drug (paclitaxel). These hydrophobic materials interact to form a hydrophobic bond in the environment of the artery. . . Hydrophobic coupling retains the drug on the surface of the polymer layer so that the drug is delivered to the tissue, which contains hydrophobic binding sites.

Infringement Contentions at 6.

The chemical coupling between the hydrophobic polymer layer and the hydrophobic treating material is a type of chemical bond. This bond adheres the drug to the polymer until the polymer layer is placed next to the tissue. The layer then releases the treating material to the tissue.

*Id.* at 8.

. . . The polymer layer contains small pores within the polymer from which the drug elutes to the surface of the polymer. The drug is released from mechanical micropores and also from a chemical hydrophobic coupling on the tissue side of the device. . .

*Id.* at 7.

Saffran's Infringement Contentions encompass the cited passage of Dr. Freeman's opinion to which BSC objects. Accordingly, the court rejects BSC's argument that Saffran *de facto* amended

its Infringement Contentions via its expert report.

### **C. New Prior Art References**

BSC added the following prior art references in its Amended Invalidity Contentions: Lambert '246, Ding, Lambert PCT, Dev Abstract, Dev Article, 1993 Lambert Abstract, 1994 Lambert Abstract and a collection of information that the parties refer to as the “work” of Dev and Lambert. In the Chart, BSC claims that it added these references in light of the court’s claim construction order. For the reasons previously mentioned, the court rejects the argument that BSC amended its Invalidity Contentions in good faith as a result of the court’s claim construction order.

BSC argues that it cured any prejudice to Saffran by belatedly adding Drs. Lambert and Dev to their trial witness list and making those witnesses available for deposition.<sup>8</sup> This scenario is similar to the previously addressed addition of Invalidity Defenses. Here, BSC asks the court to allow it to improperly add prior art references to its Invalidity Contentions because it untimely identified witnesses on its trial witness list. Additionally, BSC uses the fact that Saffran declined to depose these belatedly identified “fact” witnesses—less than six weeks from jury selection—who have authored multiple papers and patents related to a subject that is intensely contested in this case to show that Saffran would suffer no prejudice. The court will not reward violating the Federal Rules of Civil Procedure and the Local Rules of this court.

Finally, BSC argues that the prior art references added in the Amended Invalidity Contentions simply are not “a new addition to BSC’s Invalidity Contentions.” Opp. Brf. at 8. The basis for this statement seems to be that an “article naming both Drs. Lambert and Dev as authors and a patent,

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<sup>8</sup> The court questions BSC’s intent to call Drs. Dev and Lambert only as fact witnesses as opposed to soliciting opinion testimony from them..



U.S. Patent No. 5,562,922, naming Dr. Lambert as the sole inventor, were included in BSC's original Invalidity Contentions." *Id.* The court does not agree with BSC's assessment. It does not follow that disclosing an article jointly authored by Drs. Dev and Lambert and a patent for which Dr. Lambert is the sole inventor means that a litany of other references disclose nothing new. Indeed, if that were the case, then it is not clear why BSC would have believed it necessary to list them in the Amended Invalidity Contentions. In short, BSC has offered no tenable argument for adding prior art references it knew, or should have known about, before the deadline for disclosing its Invalidity Contentions.

### **III. MOTION FOR LEAVE**

BSC asks the court to grant it leave to add the Ding patent to its Invalidity Contentions. BSC owns the Ding patent and asserted it against Cordis in the U.S. District Court for the District of Delaware in 2003. On October 9, 2007, Saffran filed suit against Cordis and Johnson & Johnson accusing the Cypher Sirolimus-eluting Coronary Stent (the same stent found to infringe the Ding patent in Delaware) of infringing the '760 patent.

On October 23, 2007, BSC served Dr. Hopfenberg's expert report, which discussed the Ding patent "as it relates to the validity of the asserted claims of the '760 patent." Opp. Brf. At 13. Saffran's experts, Dr. Freeman and Dr. Jamison "discuss[ed] the Ding patent and/or respond[ed] to Dr. Hopfenberg's assertions regarding the validity of the '760 patent in light of Ding." *Id.* Of course, BSC uses this as evidence that Saffran will suffer no prejudice.

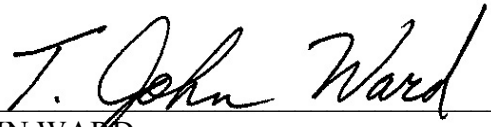
Once again, BSC offers the court no justifiable reason for the delay in disclosing a patent that BSC clearly knew about before October 23, 2007. BSC added the Ding patent in this case only after Saffran filed suit against Cordis and admits as much in its reply to Saffran's opposition to the Motion

for Leave. Specifically, BSC states in part that “[i]t was not until Saffran filed his complaint against Cordis on October 9, 2007 that BSC could make this argument.” Reply Brf. At 3. This argument is without merit. BSC had a duty to disclose the prior art upon which it sought to base its invalidity argument. Its conduct in failing to list the Ding patent is nothing if not consistent with its approach to the rest of its invalidity case. The court rejects its Motion for Leave.

#### **IV. CONCLUSION**

The court GRANTS the Motion to Strike and DENIES the Motion for Leave. The court rejects BSC’s arguments for amending its Invalidity Contentions. The court hereby strikes BSC’s Amended Invalidity Contentions and the corresponding portions of Dr. Hopfenberg’s expert reports.

SIGNED this 28th day of January, 2008.

  
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T. JOHN WARD  
UNITED STATES DISTRICT JUDGE